LORATADINE SYRUP

5 mg per 5 mL

PRODUCT COMPARISON

<u>Reference Listed Drug Product</u> Claritin® Syrup – Hives relief <u>Proposed Drug Product</u> <u>Loratadine Syrup – Hives Relief</u>

Product Name:

Claritin® Syrup

Hives Relief Syrup

Loratadine Syrup Hives Relief

Indications:

Claritin[®] Hives Relief Syrup is used for the relief of itching due

to hives (urticaria).

Loratadine Syrup is used for the relief of the relief of itching due

to hives (urticaria).

Route of

Administration:

Oral

Oral

Dosage Form:

Liquid

Liquid

Strength:

5 mg per 5 mL

5 mg per 5 mL

Bio-equivalency:

Since the product is a clear liquid like RLD, bio-equivalency requirement is waived under the regulation of 21CFR Section 320.22